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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,053	09/26/2003	Arnold R. Leiboff	461.1005	7183
22846 7590 11/12/2008 BRIAN ROFFE, ESQ. 11 SUNRISE PLAZA, SUITE 303 VALLEY STREAM, NY 11580-6111				
EXAMINER				
CHAPMAN, GINGER T				
ART UNIT		PAPER NUMBER		
3761				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/672,053

Applicant(s)

LEIBOFF, ARNOLD R.

Examiner

Ginger T. Chapman

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 40-42, 44, 66-68, 78 and 80-95 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 9, 80 and 82-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 85-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

1. Claims 5, 89, 91 and 92 are amended, claims 18-39, 43, 45-65, 69-77 and 79 are canceled, claims 1-17, 40-42, 44, 66-68, 78 and 80-95 are pending in the application, claims 2-4, 9, 80 and 82-84 are withdrawn from consideration as being drawn to a nonelected invention, claims 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 85-95 are examined on the merits.

2. **Withdrawn rejections:**

3. The rejection of Claims 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 85-95 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application No. 11/189,305 is withdrawn in view of the abandonment of '305 on file date August 20, 2008.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1, 5-8, 13-17, 40-42, 44, 66-68, 78, 81, and 85-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al (US 5,443,445) in view of Leiboff (US 4,637,814).
7. With respect to claim 78, as best depicted in Figures 2 and 4, Peters teaches a tube for attaching to a bowel, comprising a tubular body (10) having a front end adapted to be inserted into a bowel. Peters disclosed the claimed device except for a sewing ring. Peters teaches the free edge of the bowel is secured to annular collars by straps or ligatures as follows: axially spaced circumferentially extending annular collars 24, 28 extend around the tubular body 10 at the portion of the tubular body inserted into the bowel. Peters teaches the collars 28 have a portion 26 which projects outward away from the body such that the bowel is attachable to the collars 28 by passing cables straps or ligatures (c. 4, ll. 2-3) through the bowel and the collars through eyes / holes 27, 28 provided in the circumferentially extending collars ridge 26, 28 (c. 3, ll. 54-59) for securing the drain tube to the bowel (c. 3, ll. 46-50). Thus Peters provides motivation for securing the bowel to the device.
8. As best depicted in Figures 27, 28, 26e and 29, Leiboff teaches an apparatus for intestinal irrigation comprising a tube and side arm wherein the double side arm drain tube 220 has a modified distal end. Leiboff teaches that in place of the expandable cuff (fig. 27) or proximal to the cuff 25 (fig. 28), a fabric cuff 222 is provided to which the free edge of a bowel is sewn as depicted in Figure 26e to form a water tight seal (c. 20, ll. 57-68). Leiboff additionally teaches another modification in which the drain tube can be molded with a circumferential groove or channel 224 either near the distal tip of the drain tube in place of or in addition to an expandable

cuff for receiving a tube clamp 226 placed around the bowel end over the drain tube, said clamp and groove may also be used in conjunction with the cloth cuff. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the annular rings/ collars of Peters by utilizing a sewing cuff as taught by Leiboff since Leiboff states, at c. 20, ll. 60-61, that the benefit of such a modification is that it provides a water tight seal such that effluent from the bowel does not contaminate other areas of the operating field, thereby providing a cleaner more sanitary intestinal irrigation device.

9. With respect to claim 81, Peters discloses the claimed invention except for the bowel is clamped to the sewing ring. As best depicted in Figure 29, Leiboff teaches the bowel is clamped 226 to drain tube 220 in addition to the sewing cuff 222 (c. 20, ll. 61-68). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to clamp the tube and sewing cuff/ ring as taught by Leiboff in the device of Peters since Leiboff states, at c. 21, ll. 3-10, that the benefit of the clamp is that it allows a surgeon to seal the tube and irrigate the bowel.

10. With respect to claim 85, Peters teaches that the circumferentially extending collars 26, 28 are arranged around the circumference of the tubular body 10 in substantially the same location as the claimed sewing ring and performs the substantially identical function of providing a ring to which the bowel can be secured to the drain tube by ligatures, i.e. sewing or by cable straps.

11. With respect to claim 86, Peters teaches the body 10 has a proximal end adapted to be inserted into the bowel and a distal end, and the projecting portion 26 of the collars 28 projecting toward the distal end (fig. 2).

12. With respect to claim 87, Peters teaches the collars 24, 28 circumferentially extend outward from the tubular body, thereby creating notches at the juncture between the collars and the body, which are fixed relative to one another and perform the substantially identical function of the instant claimed notch.

13. With respect to claims 68 and 88, Peters discloses the claimed invention except for expressly disclosing the ring, i.e. the collars are monolithic, i.e. formed in one piece. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the collars / rings of Peters formed either monolithically or separably since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 US 164 (1893).

14. With respect to claims 66 and 89, Peters teaches a side arm 12 extending from a side of the body 10 and the side arm 12 being adapted to mate with an outflow tube 3 at a distal end and the attachment collars /rings 24, 28 arranged proximate the distal end of the body for securing the body within an open end of the severed bowel (figs. 2 and 4).

15. With respect to claim 90, Peters teaches a tie seat 26 for supporting a tie 29 used to tie the bowel around the body. With respect to the limitation the ring is part of a unitary device, see claims 68 and 88, *supra*.

16. With respect to claims 5, 67 and 91-92, as best depicted in Figure 6, Peters teaches sheath 3 (c. 3, ll. 19-20) separate from the attachment device 24, 26, 28 and is arranged rearward of the rings/ collars and having rolled and unrolled positions. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a sheath in the

claimed location since Peters states, at c. 3, ll. 19-22, that the benefit of forming the device with a sheath is that the sheath provides a cover that envelopes the a tube thereby allowing the drain tube to be gripped without exposing the user of the device to bowel effluent and it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

17. With respect to claims 6, 7 and 93, Peters teaches ridge 26 is circumferential, extending outward from an outer circumferential surface of the body 10.

18. With respect to claim 95, reciting the ring is monolithic, see claims 68 and 88, *supra*.

19. With respect to claims 1, 13-17, 40-42 and 44, Peters discloses the claimed invention except for the circumferential triangular lips angled forward to facilitate insertion of the tube into the bowel. As noted *supra*, Peters teaches circumferentially extending annular collars through which either cables straps or ligatures can be threaded or sewn for securing the drain tube to the bowel (fig. 3). As best depicted in Figures 2 and 4, Peters teaches the rings / collars comprise rounded surfaces; such rounded surfaces would facilitate insertion of the tube into the bowel because the rounded surfaces would easily slide into a bowel because there are no sharp or abrupt edges which would stop or impede the insertion thereof. Therefore it would have been an obvious matter design choice to triangular lips angled forward or rounded surfaces since both perform the substantially identical function of providing a surface which may be smoothly inserted into a bowel and it appears that the device would work equally well with the rounded edges of the rings/ annular collars of Peters and if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. *In re Schreiber*, 128 F.3d, 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

20. With respect to claims , 40-42, 66 and 89, as best depicted in Figures 1, 2 4, and 6, Peters teaches sidearm (12) extending form a side of the body (10) having a proximal end (11) adapted to be inserted into a bowel and the side arm (12) being adapted to mate with an outflow tube (3) at a distal end.

21. With respect to claims 5-8, 67 and 91-93, as best depicted in Figure 6, Peters teaches sheath (c. 3, ll. 19-20) which covers the tube (3). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a sheath in the claimed location since Peters states, at c. 3, ll. 19-22, that the benefit of forming the device with a sheath is that the sheath provides a cover that envelopes the a tube thereby allowing the drain tube to be gripped without exposing the user of the device to bowel effluent and it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

22. With respect to claims 13-15, 41, 42 and 44, Peters discloses the claimed invention except for a plurality of triangular lips. As best depicted in Figures 1, 2 4 and 6, Peters teaches collars (24) and recesses (25) for securing the device within the bowel. It would have been an obvious matter of design choice to use lips instead of collars since Applicant has not disclosed the lips solve any stated problem and it appears that the invention would work equally well with the collars disclosed in Peters since Peters states, at c. 4, ll. 20-25, that this ensures the bowel is held securely to the device.

23. With respect to claims 8 and 94, Peters discloses the claimed invention except for the sheath is made of molded latex or silicone and the ring made of soft pliable material. Peters teaches the sheath 3 (fig. 6) is flexible material, thus providing motivation for flexible material.

Latex and silicone are well-known for being flexible and pliable materials suitable for medical devices. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the sheath of flexible material as taught by Peters, said flexible material including latex and silicone known for being flexible and suitable for medical devices, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

24. With respect to claim 10, Peters discloses the claimed invention except for the body is formed from an injection molding process. The method of forming the device is not germane to the patentability of the device itself; therefore this limitation does not lend additional patentable weight.

25. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters in view of Leiboff and further in view of Kaplan et al (US 3,908,660).

26. With respect to claim 11, Peters discloses the claimed invention except for the body is transparent. Kaplan, at c. 1, l. 60, teaches the ability of the body of the device to be transparent, thus providing motivation for such. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the body of Peters transparent as taught by Kaplan since Kaplan states at c. 3, ll. 33-36, that the advantage of providing a transparent body is that it allows a laser beam to be used to form a slit in the colon wall.

27. With respect to claim 12, Peters discloses the claimed invention except for at least one thread for mating with a screw cap. As best depicted in Figure 1, Kaplan teaches at least one

thread (54) for mating with a screw cap (52). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the device of Peters with a thread and screw cap as taught by Kaplan since Kaplan states, at c. 2, ll. 15-17, that the advantage to forming the device with this design is that the threads hold the components together.

Response to Arguments

28. Applicant's arguments filed August 13, 2008 have been fully considered but they are not persuasive. Applicant argues the following:

29. It is not obvious to use circumferentially extending collars and straps instead of a sewing ring and ligatures. The sewing ring solves problems and performs better than the collars of Peters. Reliance on the ligatures of Peters is misplaced since the ligatures are not sewn during surgery. Remarks, p. 10, problems identified on p. 11.

30. These arguments are not persuasive, as detailed *supra*, for the following reasons.

31. The collars of Peters are located in the substantially same location as the claimed ring, and perform the substantially identical function of providing a ring to which the bowel can be secured to the drain tube by ligatures, i.e. sewing or by cable straps.

32. The problems identified by Applicant, movement of the bowel before it is attached or slippage of the bowel from the tube appears to be solved by Peters in the substantially identical manner, i.e. by securing the bowel to the tube by providing rings or collars to which the bowel can be sewn by ligatures as claimed, and also by securing the bowel by cable straps, taught to be an equivalent method by Peters.

33. Applicant has not provided any evidence, such as the results of clinical trials, that the collars of Peters, when sewn to the bowel by ligatures, would perform differently than the instant claimed ring. Therefore the rejection stands.

Conclusion

34. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
11/03/08

***/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761***